



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Keating et al.

Serial No: 09/554,996

Filed: May 24, 2000

For: Elastin-Based Compositions

Attorney Docket No. HYDR-P01-002

Art Unit: 1632

Examiner: S. Chen

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 35 U.S.C. §1.132 of Dean Li

Sir:


I, Dean Li of Utah, hereby declare as follows:

1. I am an employee of the University of Utah. The University of Utah has previously assigned all rights in this application to the University of Utah Research Foundation, the assignee of record.
2. Experiments were performed in collaboration with me, the results of which are depicted in Exhibit 1, which demonstrates that a stent coated with an elastin-based composition including six repeats of the hexameric sequence VGVAPG inhibited restenosis when placed into rabbit carotid arteries. The ability of the elastin coated stent to inhibit restenosis *in vivo* was assessed by measuring average lumen area twenty-eight days after stent placement, and comparing this average lumen area to that of arteries in which non-elastin coated stents were inserted.

Exhibit 1 shows the results of a study designed to assess the ability of stents coated with an elastin-based composition to prevent restenosis. One of the following stents was placed into the carotid artery of a rabbit: a bare metal stent, a poly-l-lactic acid/phosphatidylcholine (PC/PLLA) coated stent, or a stent coated with both PC/PLLA and an elastin-based composition including 6 repeats of the hexameric sequence VGVAPG. After twenty-eight days, the level of restenosis was analyzed by measuring the average lumen area of the stented artery. As demonstrated by the data summarized in Exhibit 1, the artery stented with a device coated with an elastin-based composition (the right-most bar in Exhibit 1) had the largest average lumen area. The difference in average lumen area between the artery stented with a device coated with the elastin-based composition and the artery stented with either the uncoated metal device (the left-most bar in Exhibit 1) or the artery stented with the PC/PLLA coated device (the middle bar in Exhibit 1) was statistically significant.

3. The above experiments were performed in accord with the teachings of the abovementioned patent application.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.


Dean Li

Dated: 10/05/03

